IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

PAULA CAROLE CLOWE and AUDIE L. POPE,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**Civil Action No. 3:20-cv-1702-L**
	§	
ETHICON INC. and JOHNSON & JOHNSON,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the court are Defendants' Motion for Summary Judgment (Doc. 152), filed March 1, 2021; Defendants' Motion to Exclude Certain Opinions of Dr. Daniel Elliott (Doc. 155), filed March 1, 2021; Defendants' Motion to Exclude the Case-Specific Opinions of Vladimir Iakovlev, M.D. (Doc. 158), filed March 1, 2021; Defendants' Motion to Strike the Case-Specific Opinions and Testimony of Dr. Vladimir Iakovlev for Failure to Comply with PTO 121 (Doc. 161), filed March 1, 2021; and Plaintiffs' Motion to Exclude the General Causation Opinions of Defense Expert Christina Pramudji, M.D. (Doc. 164), filed March 1, 2021. After careful consideration of the motions, responses, replies, appendixes, record, and applicable law, the court **grants in part** and **denies in part** Defendants' Motion for Summary Judgment (Doc. 152); **denies** Defendants' Motion to Strike the Case-Specific Opinions and Testimony of Dr. Vladimir Iakovlev for Failure to Comply with PTO 121 (Doc. 161); and **denies without prejudice** Defendants' Motion to Exclude Certain Opinions of Dr. Daniel Elliott (Doc. 155), Defendants' Motion to Exclude the Case-Specific Opinions of Vladimir Iakovlev, M.D. (Doc. 158), and Plaintiffs' Motion to Exclude the General Causation Opinions of Defense Expert Christina Pramudji, M.D. (Doc. 164).

I. Procedural and Factual Background

Plaintiff Paula Carole Clowe ("Clowe") is one of the tens of thousands of individuals who have filed suit against Johnson & Johnson ("J&J)" and Ethicon Inc., a wholly owned subsidiary of J&J (collectively, "Ethicon") for injuries allegedly sustained after medical treatment with Ethicon's transvaginal pelvic mesh devices. *See, e.g.*, *Fox v. Ethicon, Inc.*, 2016 WL 3748509 (S.D.W. Va. July 8, 2016); *Bell v. Ethicon, Inc.*, No. 4:20-cv-3678, 2021 WL 1111071, at *1 (S.D. Tex. Mar. 31, 2021). Her spouse, Audie L. Pope ("Pope"), is also a plaintiff in this case.[1] Clowe is a Texas resident who underwent surgery for stress urinary incontinence. Specifically, on August 23, 2004, at Baylor Medical Center in Garland, Texas, Dr. Glynn Pickens implanted Ethicon's Gynecare tension-free vaginal tape ("TVT") device in Clowe to treat her stress urinary incontinence. Am. Short Form Compl. ¶¶ 8-12, Doc. 13; Plaintiff Fact Sheet ("PFS"), Defs.' Ex. A, Doc. 154 at 3; Dep. of Dr. Daniel Elliott, Defs.' Ex. B, Doc. 154 at 52:14-53:6.[2] On February 27, 2012, Dr. Meredith Lightfoot performed an excision to remove a portion of the TVT device. PFS, Defs.' Ex. A, Doc. 154 at 4. On August 3, 2012, Dr. Joseph Schaffer performed a second excision of the TVT device. *Id.* Since her surgery, Clowe has suffered a varied and chronic set of symptoms that she contends were caused by the TVT device. Am. Short Form Compl. ¶¶ 8-12, Doc. 13; PFS, Defs.' Ex. A, Doc. 154 at 4-5.

Clowe filed this suit on September 7, 2012, in County Court of Law No. 5, Dallas County, Texas, and Ethicon subsequently removed the suit to federal court based on diversity of citizenship and because the amount in controversy, excluding interest and costs, exceeded $75,000. Defs.'

[1] On August 6, 2013, Clowe filed an Amended Short Form Complaint adding her spouse, Audie L. Pope, as a Plaintiff asserting loss of consortium. Doc. 13.

[2] Unlike the other citations in this order, which refer to CM/ECF-assigned page numbers, citations to deposition transcripts refer to the page numbers printed in the transcript.

Notice of Removal, Doc. 1. In a nutshell, Plaintiffs maintain that the TVT device was defective and unreasonably dangerous because of (i) its design and (ii) defects in the TVT device that caused Clowe serious injuries. Plaintiffs also maintain that Ethicon failed to provide adequate warnings with the TVT device.

Plaintiffs' claims were consolidated into the Ethicon Multidistrict Litigation ("MDL"), one of seven other pelvic mesh implant MDLs that included over 100,000 cases adjudicated by Judge Joseph R. Goodwin in the Southern District of West Virginia. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-6893, MDL 2327 (S.D.W. Va.). This case was initially adjudicated as part of Ethicon MDL's Wave 5 but was subsequently adjudicated as part of Wave 12. *See* Pretrial Order, Doc. 24; Joint Status Report and Discovery/Case Management Plan, Doc. 145. In October 2017, while the case was pending in the MDL court, Ethicon filed a motion for partial summary judgment and several motions to strike expert testimony. In November 2019, Plaintiffs filed a motion to strike certain expert testimony. On June 17, 2020, the MDL court issued its Order and Suggestion of Remand (Doc. 104), and on June 26, 2020, the case was remanded to this court and reopened as Civil Action No. 3:20-cv-1702-L. *See* Doc. 125. When Judge Goodwin remanded the case to the undersigned, Ethicon's motion for partial summary judgment and the parties' motions to strike experts were pending and fully briefed. Rather than rule on potentially stale motions or on motions specific to the MDL proceedings, the court denied the then-pending motions without prejudice. Order, Doc. 134.

On August 6, 2020, pursuant to the court's directive, the parties filed a Joint Status Report. Doc. 145. On October 7, 2020, the parties filed a "Joint Chart Showing Relevant *Daubert* Filings, Ruling, and Undecided Issues." Doc. 148. On March 1, 2021, Ethicon filed a renewed motion for summary judgment and refiled the motions to strike expert testimony that were not ruled upon by

the MDL court. Docs. 152, 155, 158, 161. On March 1, 2021, Plaintiffs refiled their motion to strike expert testimony that was not ruled upon by the MDL court. Doc. 164. The motions have been fully briefed and are ripe for disposition.

II. Abandoned Claims

Ethicon asserts in its motion for summary judgment that Plaintiffs abandoned or withdrew certain of their claims in their response to Ethicon's motion for partial summary judgment filed in the MDL court. The court agrees.

In Plaintiffs' Amended Short Form Complaint, Plaintiffs brought the following claims against Ethicon: negligence (Count I); strict liability—manufacturing defect (Count II); strict liability—failure to warn (Count III); strict liability—defective product (Count IV); strict liability—design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); loss of consortium (Count XVI); punitive damages (Count XVII); and discovery rule and tolling (Count XVIII). Am. Short Form Compl., Doc. 13.[3]

In the MDL court, on October 8, 2017, Ethicon moved for partial summary judgment on numerous of Plaintiffs' claims. Mot. Partial Summ. J. 1-2, Doc. 57. In their response, filed in the MDL court on October 22, 2017, Plaintiffs took the position that they would not be pursuing these claims:

[3] The court takes note that Ethicon is not moving for summary judgment on the claims of "discovery rule and tolling" (Count XVIII), "punitive damages" (XVII), and "res ispa loquitur" (Other Counts). Ethicon states that it is not moving for summary judgment on these claims "because these are not independent claims, but instead legal doctrines affecting the limitations period, elements of recovery, or types of relief." Defs.' Summ. J. Br. 1 n.1, Doc. 153.

> Defendants' motion for partial summary judgment is largely unopposed. Plaintiffs concur with Defendants that Texas substantive law applies to this case. Plaintiffs further state that they will not pursue the following claims, which are the subject of Defendants' motion: strict liability—manufacturing defect (Count II); negligence and gross negligence, to the extent premised on allegations of manufacturing defect (Counts I and XIV); strict liability—defective product (Count IV) (except to the extent it is encompassed in Plaintiffs' design defect or failure to warn claims); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent infliction of emotional distress (Count X); breach of express and implied warranty (Counts XI and XII); violation of consumer protection laws (Count XIII); and unjust enrichment (Count XV).

Pls.' Mem. Opp. Defs.' Mot. Partial Summ. J., Doc. 66.

Having considered Plaintiffs' response to Ethicon's motion for partial summary judgment at the MDL stage, the Court agrees with Ethicon that Plaintiffs abandoned the following claims at the MDL stage: strict liability—manufacturing defect (Count II); negligence and gross negligence—manufacturing defect (Counts I and XIV); strict liability—defective product (Count IV) (except to the extent it is encompassed in Plaintiffs' design defect or failure to warn claims); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent infliction of emotional distress (Count X); breach of express and implied warranties (Counts XI and XII); violation of consumer protection laws (Count XIII); and unjust enrichment (Count XV). As Plaintiffs have voluntarily withdrawn and abandoned these claims, they are **dismissed with prejudice**, and Ethicon's motion for summary judgment on these claims is **denied as moot**.

III. Defendants' Motion for Summary Judgment

Ethicon moves for summary judgment on the remaining claims: negligence and strict liability for design defect (Counts I and III), and negligence and strict liability for failure to warn, as well as fraud and negligent misrepresentation related to the failure-to-warn claim (Counts I, III,

VI, and IX).[4] The parties agree that Texas law applies to the remaining claims, and the court accepts the parties' reasoning and will apply Texas law.

A. Standard of Review

Summary judgment shall be granted when the record shows that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986); *Ragas v. Tennessee Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir. 1998). A dispute regarding a material fact is "genuine" if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When ruling on a motion for summary judgment, the court is required to view all facts and inferences in the light most favorable to the nonmoving party and resolve all disputed facts in favor of the nonmoving party. *Boudreaux v. Swift Transp. Co., Inc.*, 402 F.3d 536, 540 (5th Cir. 2005). Further, a court "may not make credibility determinations or weigh the evidence" in ruling on a motion for summary judgment. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *Anderson*, 477 U.S. at 254-55.

Once the moving party has made an initial showing that there is no evidence to support the nonmoving party's case, the party opposing the motion must come forward with competent summary judgment evidence of the existence of a genuine dispute of material fact. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 586 (1986). On the other hand, "if the movant bears the burden of proof on an issue, either because he is the plaintiff or as a defendant he is asserting an affirmative defense, he must establish beyond peradventure all of the essential elements of the claim or defense to warrant judgment in his favor." *Fontenot v. Upjohn Co.*, 780

[4] Although listed as separate counts, Plaintiffs' negligence, gross negligence, fraud, and negligent misrepresentation claims are effectively additional theories of liability for design defect and failure to warn.

F.2d 1190, 1194 (5th Cir. 1986) (emphasis in original). "[When] the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine [dispute] for trial.'" *Matsushita*, 475 U.S. at 587 (citation omitted). Mere conclusory allegations are not competent summary judgment evidence, and thus are insufficient to defeat a motion for summary judgment. *Eason v. Thaler*, 73 F.3d 1322, 1325 (5th Cir. 1996). Unsubstantiated assertions, improbable inferences, and unsupported speculation are not competent summary judgment evidence. *See Forsyth v. Barr*, 19 F.3d 1527, 1533 (5th Cir. 1994).

The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports his or her claim. *Ragas*, 136 F.3d at 458. Rule 56 does not impose a duty on the court to "sift through the record in search of evidence" to support the nonmovant's opposition to the motion for summary judgment. *Id.*; *see also Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 915-16 & n.7 (5th Cir. 1992). "Only disputes over facts that might affect the outcome of the suit under the governing laws will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 248. Disputed fact issues that are "irrelevant and unnecessary" will not be considered by a court in ruling on a summary judgment motion. *Id.* If the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to its case and on which it will bear the burden of proof at trial, summary judgment must be granted. *Celotex*, 477 U.S. at 322-23.

B. Analysis

1. Design Defect Claim

Ethicon moves for summary judgment on Plaintiff's design defect claim. Ethicon contends that "Plaintiffs' claims related to a purported defect in design, whether in negligence or strict liability, should be dismissed because Plaintiffs fail to show that a safer alternative design existed

that was available at the time of implant and would have been suitable to treat Ms. Clowe." Defs.' Summ. J. Br. 1, Doc. 153. Ethicon further maintains that "Plaintiffs have failed to show that alternative designs were available and were not completely different surgeries or devices." *Id.* at 7. In response, Plaintiffs contend that "[s]ummary judgment is inappropriate because [they] have presented sufficient evidence of viable alternative designs that, under Texas law, would allow a reasonable factfinder to conclude a safer design existed before 2004." Pl.'s Summ. J. Resp. Br. 3, Doc. 169.

To establish a design defect, a plaintiff must prove that "(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 765 (5th Cir. 2018) (quoting *Casey v. Toyota Motor Eng'g & Mfg. N.A.*, 770 F.3d 322, 330 (5th Cir. 2014)). A safer alternative design is one that "would have prevented or significantly reduced the risk of the claimant's personal injury without substantially impairing the product's utility," while remaining "economically and scientifically feasible." *Id.* (citing Tex. Civ. Prac. & Rem. Code § 82.005(b)). "Consistent with this risk-utility framework, a plaintiff 'must show the safety benefits from [the] proposed design are foreseeably greater than the resulting costs, including any diminished usefulness or diminished safety.'" *Id.* at 765-66 (quoting *Casey*, 770 F.3d at 331). Proof of a safer alternative design is "a prerequisite to liability" under the Texas Product Liability Statute, "as it has come to be under the common law." *Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 258 (Tex. 1999). "[I]f there are no safer alternatives, a product is not unreasonably dangerous as a matter of law." *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995).

"The Texas Supreme Court and intermediate courts have held that a 'substantially different product' cannot constitute a safer alternative design." *In re DePuy Orthopaedics*, 888 F.3d at 766 (citations omitted). Texas courts have rejected a plaintiff's "proposed alternative for failing to perform the discrete *kinds* of functions for which the alleged defective [product] was designed," as opposed to a "slight difference in *degree*—that is, that the alternative does all the things for which the allegedly defective product was designed, but does not do one of them quite as well." *Id.* at 767 (original emphasis). "Texas's risk-utility test plainly contemplates that a proposed alternative design might reduce a product's utility—that is, its capacity to perform a function for which it was designed—without rendering the alternative an entirely different product." *Id.*

The parties' briefing revolves around the second factor of the design-defect test, that is, whether Plaintiffs have produced sufficient evidence at the summary-judgment stage to raise a genuine dispute of material fact that "a safer alternative design existed." *See id.* at 765. In particular, the parties dispute whether the evidence submitted with Plaintiffs' Response (which includes Dr. Daniel Elliott's case-specific expert report and Dr. Brian Raybon's Rule 26 Expert Report), is sufficient to create a genuine dispute of material fact as to whether a safer, feasible design for the TVT device existed at the time of Clowe's surgery in 2004. Because Ethicon's only arguments concern the second factor of the design defect test, the court will not address the other elements of the test set forth in *In re DePuy Orthopaedics*.

The Gynecare TVT is a "sterile single use device consisting of one piece of undyed Prolene® polypropylene Mesh (tape) approximately ½ x 16 inches (1.1 x 40 centimeters), covered by a plastic sheath cut in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars." Dr. Elliott Case Specific Report, Pls.' Ex. D, Doc. 170-4 at 10. It was intended "to be used as a pubourethral sling for treatment of stress urinary incontinence

(SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency." *Id.* The Prolene® polypropylene mesh used for the TVT device was mechanically cut, "constructed of knitted filaments of extruded polypropylene strands," and considered "a heavyweight, small pore mesh." *Id.*, Doc. 170-4 at 10, 15. Because of these characteristics, the TVT mesh is associated with "excessive foreign body reaction, chronic inflammation, scar plate formation, and shrinkage of the mesh from bridging fibrosis." *Id.*, Doc. 170-4 at 15.

Dr. Elliott suggests four specific alternatives for the TVT: (1) "using an alternative product like a suture product, as with the Burch procedure"; (2) "using a pubovaginal sling (autologous, cadaveric, or xenograft)"; (3) using "an allograft sling, like Repliform"; and (4) using "a lighter weight, larger pore mesh sling with less Prolene material (e.g., Ultrapro) with sealed borders." Dr. Elliott Case Specific Report, Pls.' Ex. D, Doc. 170-4 at 36.

Dr. Raybon proposes a heat-sealed large pore mesh. Rule 26 Expert Report of Brian Raybon, M.D., Pl.'s Ex. E, Doc. 170-5 at 3-7. He states that "[s]ealed mesh creates smooth or beaded edges in comparison to the sharp, spike-like edges of the mechanically cut mesh" and "eliminates complications caused by the sharp edges, fraying, curling, rolling, roping, and particle loss." *Id.*

In support of summary judgment on Plaintiffs' design defect claim, Ethicon contends that "[n]one of [Dr. Elliott's] purported alternatives are sufficient to meet Plaintiffs' burden of demonstrating a safer alternative design because they do not constitute alternative designs for TVT at all." Defs.' Summ. J. Br. 7, Doc. 153. Ethicon maintains that all of Dr. Elliott's alternatives are either procedures or entirely different products. *Id.* With respect to Dr. Raybon's proposed alternative of a heat-sealed large pore mesh, in the reply brief, Ethicon contends it is a different

product or a procedure and, therefore, does not satisfy the definition of alternative product design under Texas law. Defs.' Reply Br., 2-3, Doc. 182.

As an initial matter, the court agrees with Ethicon that alternative (1) proposed by Dr. Elliott, the use of sutures in a Burch procedure, is a separate and distinct surgical procedure from the implantation of the TVT device. The MDL court has held that a Burch procedure using sutures to perform the repair is "not an alternative, feasible design for the TVT as a matter of law." *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 943 (S.D.W. Va 2017). Under Texas law, Plaintiffs must propose a safe and feasible alternative design to the alleged defective design, not different procedures or strategies entirely. *Causey*, 770 F.3d at 331; *Caterpillar*, 911 S.W. 2d at 384. As stated by the MDL Court, "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists." *In re Ethicon, Inc. Pelvic Repair Sys Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D. W. Va. Mar. 29, 2017). Accordingly, to the extent Plaintiffs' design defect claim is based on alternative (1) proposed by Dr. Elliott, the use of sutures in a Burch procedure, there is no genuine dispute of material fact. Ethicon, therefore, is entitled to judgment as a matter of law, and the court will enter summary judgment in favor of Ethicon with respect to proposed alternative (1).

With respect to Dr. Elliott's proposed alternatives (2) and (3)—a pubovaginal sling using tissue from human or animal cadavers, or an allograft sling, like Repliform —Plaintiffs contend, and the summary judgment record supports, that these alternatives were made of non-synthetic materials, including animal or human tissues and that these alleged safer designs were available at the time of implantation. Ethicon contends these alternatives are not safer, alternative designs because they are not made from synthetic mesh and are, therefore, an entirely different product. In addition, Ethicon asserts these are alternative procedures and not products. For the reasons that

follow, the Court determines that Plaintiffs have provided sufficient evidence to raise a genuine dispute of material fact that Dr. Elliott's proposed alternatives (2) and (3) constitute safer alternative designs to the TVT device.

In Texas, a plaintiff cannot prove a safer alternative design exists by pointing to a substantially different product despite both products serving the same general purpose. *Brockert v. Wyeth Pharmaceuticals, Inc.*, 287 S.W.3d 760, 770 (Tex. App.—Houston [14th Dist.] 2009, no pet.). Products are not substantially different, however, simply because they are comprised of different materials. *In re DePuy Orthopaedics*, 888 F.3d at 767-68 (holding that a plastic hip implant and a metal hip implant were not substantially different products). Texas uses a risk-utility test to determine if the proposed design is substantially similar to the alleged defective design. *Id.* at 767; *see* Tex. Civ. Prac. & Rem. Code § 82.005(b). The balancing test "plainly contemplates that a proposed design might reduce a product's utility—that is, its capacity to perform a function for which it was designed—without rendering the alternative an entirely different product. *Id.* This requires a fact-specific inquiry to determine whether the distinctions—such as the differences in durability and utility—create differences in the kind of function the designs have or a slight difference in degree of the same function. *Id.* at 767.

Ethicon contends that because the proposed alternatives (2) and (3) are composed of different materials from the TVT device, or are merely alternative surgical procedures, they are substantially different and do not constitute safer alternative designs. They do not cite any cases applying Texas law in support of this proposition. The Fifth Circuit has concluded that Texas law recognizes that proposed designs made of differing materials can be safer alternative designs. *See In re DePuy Orthopaedics*, 888 F.3d at 767-68 (holding that a plastic hip implant and a metal hip implant were not substantially different products). Ethicon has not shown that there are substantial

differences in the designs to render the alternatives entirely different products with differing functions. In addition, other cases applying Texas law support the court's conclusion that proposed designs made of differing materials can be safer alternative designs. *See, e.g.*, *Pizzitola v. Ethicon, Inc.*, No. 4:20-CV-2256, 2020 WL 6365545, at *5 (S.D. Tex. Aug. 31, 2020) (finding that, under Texas law, mesh products made from animal and human tissue, rather than synthetic mesh, can be safer, alternative designs to a synthetic mesh implant and denying Ethicon's motion for summary judgment on that basis); *Dalton v. C. R. Bard, Inc.*, No. 3:19-CV-2484-D, 2020 WL 1307965, at *11 (N.D. Tex. Mar. 19, 2020) (noting that expert's testimony that the mesh device at issue could have been designed differently creates "a genuine dispute over whether [the plaintiff's] suggestions for the [mesh device] amount to a safer alternative design" and denying C.R. Bard's motion for summary judgment on that basis).

With respect to Dr. Elliott's alternative (4), drawing all permissible inferences from the underlying facts in the light most favorable to Plaintiffs, the court concludes that Plaintiffs have established, via Dr. Elliott's reports as well as other evidence they provide, that whether alternative (4) is a valid safer and functional alternative design for the TVT device is a genuinely disputed material fact. The court acknowledges that Plaintiffs have not proffered extensive evidence, via Dr. Elliott's reports or otherwise, that this design (4) would "have reduced [Clowe's] injuries, would not have affected the product's utility, and would have been economically and technologically feasible." *Lankston v. Ethicon, Inc.*, No. 2:12-CV-00755, 2016 WL 5843723, at *3 (S.D.W. Va. Oct. 4, 2016). That Plaintiffs are able to point to Dr. Elliott's description of "a lighter weight, larger pore mesh sling with less Prolene® material (e.g., Ultrapro) with sealed borders" as an example of the proposed alternative design, however, strongly suggests that the design may be less harmful, as functional, and as feasible. *Cf. Caterpillar*, 911 S.W.2d at 384

("Because Shears offered no evidence of a safer design for a loader that could perform the same tasks as the Caterpillar model 920, we hold that this product is not defectively designed as a matter of law."). Further, a proposed alternative "design need only prove capable of being developed." *General Motors Corp. v. Sanchez*, 997 S.W.2d 584, 592 (Tex. 1999) (internal quotations and citation omitted). Dr. Elliott's report, coupled with other evidence provided by Plaintiffs, is sufficient to raise a genuine dispute of material fact as to whether a lighter weight, larger pore mesh sling with less Prolene® material and sealed borders is a safer alternative design.[5]

For the same reasons, the court similarly concludes that Plaintiffs have raised a genuine dispute of material fact as to whether the heat-sealed large pore mesh proposed by Dr. Raybon is a safer alternative design. Ethicon is not entitled to summary judgment on Plaintiffs' design defect claim based on the proposed alternative of a heat-sealed large pore mesh.

In summary, with the exception of Dr. Elliott's alternative (1), the Burch procedure, the court concludes that the evidence creates a genuine dispute of material fact as to whether Dr. Elliott's and Dr. Raybon's suggested alternatives for the TVT device amount to a safer alternative design. Because Plaintiffs offer evidence that the TVT device could have been designed with a lighter mesh with larger pores, a mesh with less Prolene® material, or could have been made in part with harvested tissue or native tissue, or with heat-sealed non-mechanically cut mesh, and that

[5] The court notes Ethicon's argument that "Ultrapro . . . is a mesh that has not been approved by the FDA for use in a sling product." Defs.' Summ. J. Br. 10, Doc. 153. Ethicon argues that, therefore, this hypothetical alternative "does not meet the requirement that the alternative design must have been legally available at the time the TVT was manufactured." *Id.* Dr. Elliott only cites Ultrapro as a possible example of a lighter weight, larger pore mesh sling with less Prolene® material and sealed borders. Plaintiffs do not dispute that Ultrapro is a mesh that has not been approved by the FDA for use in a sling product. The court, therefore, will not permit Plaintiffs' experts to rely on Ultrapro as a safer alternative design, but will permit testimony concerning a lighter weight, larger pore mesh sling with less Prolene® material as a safer alternative design as long as that product has been FDA-approved. *See, e.g., Pizzitola v. Ethicon, Inc.*, 2020 WL 6365545, at *5 (S.D. Tex. Aug. 31, 2020) (rejecting as safer alternative designs mesh devices that had not been cleared by the FDA at the time of surgery).

these design alternatives would have made the TVT device a safer product, the court denies Ethicon's motion for summary judgment as to Plaintiffs' design defect claim based on negligence and strict liability.

2. Failure to Warn Claims

The court now turns to Ethicon's motion for summary judgment as to Plaintiffs' failure to warn claims. Ethicon contends that these claims "fail as a matter of law because Ethicon's allegedly inadequate warning was not the producing cause of Plaintiffs' injuries." Defs.' Reply Br. 4, Doc. 182.

Ethicon invokes the learned intermediary doctrine, which provides that "[w]hen the prescribing physician is aware of the product's risks and decides to use it anyway, any inadequacy [in] the product's warning, as a matter of law, is not the producing cause of the patient's injuries." *In re DePuy Orthopaedics*, 888 F.3d at 774 (quoting *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 163 (Tex. 2012)). To overcome application of the doctrine, Plaintiffs must present evidence that (1) "the doctor would have read or encountered the adequate warning; and [(2)] that the adequate warning would have altered his treatment decision for, or risk-related disclosures to, the patient." *Id.* at 775.

Ethicon argues that Clowe's implanting physician, Glynn Pickens, M.D., testified at his deposition that, even had he received adequate or different warnings regarding adverse effects of the TVT device, it would not have changed his mind regarding the desired treatment for Clowe. Review of Dr. Pickens's deposition testimony shows that he knew of the risks about which Plaintiffs now complain. Clowe complains of bleeding and spotting, chronic shooting pains, pain during sexual intercourse, and inability to sit or walk for long periods of time as injuries from implantation of her TVT device. PFS, Defs.' Ex. A, Doc. 154 at 4-5. Dr. Pickens knew about these

risks from TVT implantation before he implanted the TVT device in Clowe. Dep. of Glynn Pickens, M.D., Defs.' Ex. B, Doc. 154 at 70:1-73:21. He testified that he was aware of the risks of TVT, including: "[a]cute and/or chronic pain with intercourse, acute and/or chronic pain, vaginal scarring, infection, urinary problems, organ/nerve damage, bleeding, wound complications, inflammation, fistula formation, neuromuscular problems, one or more surgeries to treat an adverse event, recurrence or failure, foreign-body response to sutures, erosion/exposure/extrusion of sutures, contraction/shrinkage of tissues." *Id.* at 70:1-11. Dr. Pickens also testified that he did not rely on Ethicon to acquire knowledge and understanding of the risks of TVT. *Id.* at 75:22-76:1. Rather, according to Dr. Pickens, he learned of the risks of the TVT device from medical literature, discussions with his colleagues, his clinical experience, and reviews of procedures. *Id.* at 73:22-75:21. With respect to the instructions for use ("IFU") that accompany the TVT device, Dr. Pickens testified that he would not expect the IFU to educate him on how to perform the surgery or to supplant his knowledge as a surgeon that he has obtained through his experience. *Id.* at 70:13-20. Dr. Pickens testified that the last time he read a TVT IFU was around 2002 or 2003, if not before. *Id.* at 77:18-23. He further testified that even if the TVT IFU listed in detail the risks of which he was already aware, it would not have changed his recommendation to use the TVT device to treat Clowe. *Id.* at 80:9-16.

The court has considered Plaintiffs' response and viewed all evidence in the light most favorable to Plaintiffs. In their response, Plaintiffs suggest that Ethicon's IFU was inadequate at the time Dr. Pickens surgically implanted Clowe with the TVT device. *See* Pls.' Summ J. Resp. Br. 13, 15-16, Doc. 169. Ethicon's motion, however, is focused on Dr. Pickens's *knowledge as the learned intermediary* and the fact that he testified *he knew the risks* of treating Clowe at the time

of her treatment. The court agrees with Ethicon that "Plaintiffs incorrectly attempt to shift the focus to the sufficiency of the warnings Ethicon provided to Dr. Pickens." Defs.' Reply Br. 4, Doc. 182.

In their response, Plaintiffs suggest that Dr. Pickens relied on Ethicon's warnings to understand the risks associated with Ethicon's TVT device. Pls.' Summ J. Resp. Br. 16-17, Doc. 169. They maintain that Dr. Pickens's testimony "indicates that he relied to some extent on Ethicon for useful and accurate information" about the product. *Id.* at 13. In reply, Ethicon argues that "whether Dr. Pickens relied 'to some extent' on Ethicon's warnings is not the issue." Defs.' Reply Br. 5, Doc 182. The court agrees.

Plaintiffs must show that if a different warning had been given, Dr. Pickens would not have prescribed the device. *See Lewis v. Johnson & Johnson*, 601 F. App'x 205, 208 (4th Cir. 2015) (affirming grant of summary judgment under Texas law) ("When a physician relies on [his] own experience and examination of a patient in deciding to prescribe a device, and not on the device's warning, the warning is not the cause of the patient's injury."); *Fox*, 2016 WL 3748509, at *3 ("If a physician, as the learned intermediary, does not testify that he or she would not have prescribed the product, the causal chain is broken, the plaintiff cannot show causation, and the failure to warn claim fails.") (Texas law); *Centocor*, 372 S.W.3d at 142 ("[B]ecause the Hamiltons failed to present any evidence that including additional post-approval reports in the warning would have caused Patricia's physicians to change their prescription, the Hamiltons failed to meet their burden of proof."). Absent proof that the failure to warn was the producing cause of Ms. Clowe's injury, Plaintiffs cannot establish their failure to warn claims. *See Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008).

The court is also not persuaded by Plaintiffs' argument that they have raised a genuine dispute of material fact based on Dr. Pickens's statements that he would have been interested in

"looking at the differences in the complication rates between the laser-cut mesh and the TVT MC mesh." Pls.' Summ. J. Resp. Br. 17, Doc. 169. Dr. Pickens testified with unmistakable clarity that even if Ethicon's IFU contained a more detailed explanation of risks, he would have still recommended using the TVT device to treat Clowe:

> Q. Would you have -- if each of these potential risks that you and I discussed that are listed in Exhibit Number 8 were listed in the TVT instructions for use, would that have changed your recommendation to use the TVT product for Ms. Clowe?
>
> A. No.

Dep. of Glynn Pickens, M.D., Defs.' Ex. B, Doc. 154 at 80:9-16. Further, because Dr. Pickens testified that he was aware of the risks of the TVT device, any additional risks he may have learned after the fact would not have changed his decision. *See Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 817 (5th Cir. 1992) ("The burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff.").

In summary, viewing all evidence in the light most favorable to Plaintiffs, the court concludes that they have failed to raise a genuine dispute of material fact as to whether Dr. Pickens would have changed his decision to implant the TVT device had he received a different warning. For this reason, Ethicon is entitled to judgment as a matter of law, and the court grants Ethicon's motion for summary judgment as to Plaintiffs' failure to warn claim, sounding in both negligence and strict liability, as well as their derivative claims of fraud and negligent misrepresentation claims. *See Fearrington v. Boston Sci. Corp.*, 410 F. Supp. 3d 794, 808 (S.D. Tex. 2019) ("Plaintiff's negligence claim cannot rely on any alleged negligent failure to warn as this would be an impermissible circumvention of the learned intermediary doctrine and its bar on Plaintiff's failure-to-warn strict liability claim.").

3. Loss of Consortium Claims

Ethicon moves for summary judgment on Plaintiffs' loss of consortium claim arguing that it is barred because it is derivative. Defs.' Summ. J. Br. 12, Doc. 153. Because the court has denied Ethicon's motion for summary judgment with respect to Plaintiffs' design defect claim, it rejects Ethicon's argument that Plaintiffs' loss of consortium claims should be denied as derivative. *See, e.g., Gamboa v. Centrifugal Casting Mach. Co.*, 2015 WL 6835359, at *16 (S.D. Tex. Nov. 6, 2015) ("Because the court has held that Plaintiffs' other claims do not fail, Ms. Gamboa's derivative loss of consortium claim survives.").

In the alternative, Ethicon moves for summary judgment on Plaintiffs' loss of consortium claim because Plaintiffs were not married at the time of Clowe's injury. Defs.' Summ. J. Br. 12, Doc. 153. In response, Plaintiffs contend that "Ethicon does not point to any Texas authority in support" of its contention that a loss of consortium claim would require Clowe and Pope to be married at the time of the injury. Pls.' Summ. J. Resp. Br. 20, Doc. 169. According to Plaintiffs, "the parties maintained an intimate relationship before the injury occurred [and] the injuries [Clowe] suffered as a result of the surgeries still interfere with their relationship." *Id.* at 21. Ethicon concedes that "there are no Texas-specific cases that address" the issue of whether a loss of consortium claim is available when the alleged injury predated the marriage. Defs.' Summ. J. Br. 12, Doc. 153. Ethicon contends, however, that "while no Texas case has addressed whether loss of consortium is available when the alleged injury pre-dated the marriage, Texas law requires the plaintiffs to be married, and the majority of jurisdictions require that the marriage pre-date the alleged injury." Defs.' Reply Br. 7, Doc. 182.

The parties agree that Texas substantive law governs this case. "In applying Texas law, [federal courts] look first to the decisions of the Texas Supreme Court." *Kelly v. Nichamoff*, 868

F.3d 371, 374 (5th Cir. 2017) (quoting *Hux v. Southern Methodist Univ.*, 819 F.3d 776, 780 (5th Cir. 2016)). If the Texas Supreme Court has not ruled on an issue, as here, the court makes an *Erie* guess, "predicting what the [Texas Supreme Court] would do if faced with the same facts." *Ironshore Eur. DAC v. Schiff Hardin, L.L.P.*, 912 F.3d 759, 764 (5th Cir. 2019) (brackets in original) (citations omitted). When rendering an *Erie* guess, federal courts "treat state intermediate courts' decisions as the strongest indicator of what a state supreme court would do, absent a compelling reason to believe that the state supreme court would reject the lower courts' reasoning." *Hux*, 819 F.3d at 780-81.

The decisions of state intermediate appellate courts, however, are not the only factor that a federal court considers when rendering an *Erie* guess. An *Erie* guess may be predicated upon the following factors:

> (1) decisions of the state supreme court in analogous cases, (2) the rationales and analyses underlying state supreme court decisions on related issues, (3) dicta by the state supreme court, (4) lower state court decisions, (5) the general rule on the question, (6) the rulings of courts of other states to which state courts look when formulating substantive law[,] and (7) other available sources, such as treatises and legal commentaries.

Weatherly v. Pershing, L.L.C., 945 F.3d 915, 920 (5th Cir. 2019), *cert. denied*, 141 S. Ct. 236 (2020) (quoting *In re DePuy Orthopaedics*, 888 F.3d at 765 n.5). When making an *Erie* guess, federal courts do not "adopt innovative theories of state law" but rather seek to apply the law as it currently exists. *Id.* (citation omitted).

For the reasons that follow, the court concludes that, were the same facts to come before the Texas Supreme Court, it, more likely than not, would prohibit loss of consortium recovery when the alleged injury predated the marriage. "Texas first recognized an action for loss of a spouse's consortium in *Whittlesey v. Miller*, 572 S.W.2d 665 (Tex. 1978)." *Glasscock v. Armstrong Cork Co.*, 946 F.2d 1085, 1089 (5th Cir. 1991). In *Whittlesey*, the Texas Supreme Court

stated: "The marital relationship is the primary familial interest recognized by the courts. The remedy for the negligent or intentional impairment of this relationship is a tort action for loss of consortium." *Whittlesey*, 572 S.W.2d at 666. It also held that the "loss of consortium can arise from either the intentional or negligent conduct of a third party toward the marital relationship." *Id.* With respect to damages, the Fifth Circuit, analyzing Texas law, has held that direct evidence is not required. *Puga v. RCX Sols., Inc.*, 922 F.3d 285, 296 (5th Cir. 2019). As explained in *Puga*:

> A jury can infer loss of consortium damages "from [indirect] evidence showing the nature and extent of a spouse's injuries." *Glasscock*, 946 F.2d at 1090. When considering indirect evidence, juries can rely on "(1) the nature of the marital relationship prior to the spouse's injury, (2) the deterioration of the marital relationship following the injury, and (3) the extent and duration of the spouse's injuries." *Id.* (citing *Whittlesey*, 572 S.W.2d at 667; *Monsanto Co. v. Johnson*, 675 S.W.2d 305, 312 (Tex. App.—Houston [1st Dist.] 1984)).

Id. (footnote omitted).

Making an *Erie* guess, the court concludes that these cases are sufficient to indicate that the Texas Supreme Court would not entertain a loss of consortium claim when the injury predated the marriage. First, in *Whittlesey*, the court stated that the "loss of consortium can arise from either the intentional or negligent conduct of a third party *toward the marital relationship*." 572 S.W.2d at 666 (emphasis added). This statement necessarily presupposes a marital relationship in existence at the time of the third party's intentional or negligent conduct. In addition, as a practical matter, assuming a valid cause of action for loss of consortium, the court sees no path to Plaintiffs' ability to prove damages when the injury predates the marriage. As set out in *Puga*, when considering indirect evidence, juries can rely on "(1) the nature of the marital relationship prior to the spouse's injury, (2) the deterioration of the marital relationship following the injury, and (3) the extent and duration of the spouse's injuries." 922 F.3d at 296 (citations omitted). Factors (1) and (2) in *Puga* are inextricably intertwined, and, therefore, absent a marriage in existence at the time of the

impaired spouse's injuries, the court cannot conceive how a jury could measure the deterioration of the marital relationship following the injury.

Further, precluding Plaintiffs' loss of consortium claim here would be consistent with how courts in other jurisdictions have addressed the issue. *See, e.g.*, *Doe v. Cherwitz*, 518 N.W.2d 362, 365 (Iowa 1994) ("In general, courts have denied recovery for loss of consortium where the injury occurs before the marriage.") (citation omitted); *Adams v. New Rochelle Hosp. Med. Ctr.*, 919 F. Supp. 711, 717 (S.D.N.Y. 1996) (refusing to extend the discovery rule to a loss of consortium claim for a spouse who married the injured plaintiff after the injury); *see also* 1 Stein on Personal Injury Damages § 2:11 (3d ed. 2020) (explaining that the majority of courts prohibit loss of consortium recovery when the marriage occurred after the injury).

In summary, because the Texas Supreme Court has not spoken directly on whether a loss of consortium claim is available when the injury to the impaired spouse predated the marriage, the court must make its best *Erie* guess on how the Texas Supreme Court would resolve the matter. Applying the above-listed factors, and mindful that federal courts do not "adopt innovative theories of state law" but rather seek to apply the law as it currently exists, *see Weatherly*, 945 F.3d at 920, the court concludes that the Texas Supreme Court, more likely than not, would preclude a loss of consortium claim when the alleged injury predated the marriage. Accordingly, Ethicon is entitled to judgment as a matter of law, and the court grants summary judgment in Ethicon's favor on Plaintiffs' loss of consortium claim.

IV. Defendants' Motion to Strike the Case-Specific Opinions and Testimony of Dr. Vladimir Iakovlev for Failure to Comply with PTO 121

Pursuant to Federal Rules of Civil Procedure 37(b)(2) and 16(f), Ethicon moves to strike the case-specific opinions and testimony of Plaintiffs' case-specific pathology expert, Dr. Vladimir Iakovlev, and all evidence related to his examination, analysis and testing of Clowe's explanted

mesh specimen. Plaintiffs oppose the request. After setting forth the applicable law, the court will consider the parties' legal arguments and the evidence filed in support.

A. Legal Standard

The court has broad discretion in formulating sanctions for a violation of its scheduling or pretrial orders. *See Barrett v. Atlanta Richfield Co.*, 95 F.3d 375, 380 (5th Cir.1996). Under Federal Rule of Civil Procedure 16(f), the Court may, sua sponte, issue sanctions, including those authorized under Federal Rule of Civil Procedure 37(b)(2)(A)(ii)-(vii), if a party fails to comply with a pretrial order. *See* Fed. R. Civ. P. 16(f) (1) ("On motion or on its own, the court may issue any just orders, including those authorized by Rule 37(b)(2)(A)(ii)-(vii), if a party or its attorney: . . . (C) fails to obey a scheduling or other pretrial order.").

Rule 37(b)(2)(A), in turn, provides: "If a party or a party" officer, director, or managing agent—or a witness designated under [Federal Rule of Civil Procedure] 30(b)(6) or 31(a)(4)—fails to obey an order to provide or permit discovery, including an order under [Federal Rule of Civil Procedure] 26(f), 35, or 37(a), the court where the action is pending may issue further just orders. They may include the following: (i) directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action, as the prevailing party claims; (ii) prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence; (iii) striking pleadings in whole or in part; (iv) staying further proceedings until the order is obeyed; (v) dismissing the action or proceeding in whole or in part; (vi) rendering a default judgment against the disobedient party; or (vii) treating as contempt of court the failure to obey any order except an order to submit to a physical or mental examination. When considering sanctions under Rule 16(f), the court, however, should fashion remedies suited to the misconduct and should consider whether lesser sanctions,

short of contempt, dismissal, or a default judgment, may prove effective. *See, e.g., Smith & Fuller, P.A. v. Cooper Tire & Rubber Co.*, 685 F.3d 486, 488 (5th Cir. 2012).

B. Analysis

In support of the motion to strike, Ethicon contends that Plaintiffs failed to comply with Pretrial Order 121 ("PTO 121"), in which the MDL court ordered the parties "to meet and confer regarding the protocols governing the transfer, preservation, and division of mesh explants after they are released by the health care facility." PTO 121, Defs.' Ex. A, Doc. 162 at 7. Ethicon contends that "Plaintiffs did not meet and confer with Ethicon to determine how to proceed with Ms. Clowe's explanted mesh prior to allowing Dr. Iakovlev to conduct his testing and analysis." Defs.' Mem. Supp. Mot. Strike 3, Doc. 162. Ethicon further maintains that "Plaintiffs' counsel was on notice of the meet and confer requirement and did nothing to ensure that the required meet and confer took place prior to [Dr. Iakovlev's] processing of Ms. Clowe's explanted mesh." *Id.* at 4. Ethicon contends it is "highly prejudiced by this conduct, which occurred after entry of PTO 121." *Id.* Ethicon states:

> Given that no unadulterated sample of Specimen B was maintained for Ethicon, its experts are unable to conduct the testing and examination necessary to refute Dr. Iakovlev's opinions regarding the cause of Ms. Clowe's injuries. Because Specimen B contained the only sample of Ms. Clowe's explanted mesh, there is no remedy for this prejudice short of striking all of Dr. Iakovlev's case-specific opinions and testimony, as well as any other evidence or expert opinion that relies upon Dr. Iakovlev's processing, examination, analysis and testing of the explanted mesh specimen.

Id. at 4.

In response, Plaintiffs contend that Ethicon's motion is "contrary to fact, and should be denied." Pls.' Resp. Br. Mot. Strike 1, Doc. 173. They further assert that, based on the record, any "claim of prejudice to Defendants is thus far outweighed by the prejudice Plaintiffs would suffer if the motion were granted." *Id.* at 2.

Having reviewed the parties' arguments and carefully examined the copious appendixes filed by the parties, as well the chronology of events, the court, in the exercise of its discretion, concludes that sanctions are not appropriate. Specifically, the record reveals that Plaintiffs' counsel attempted to coordinate with Ethicon concerning Clowe's excised mesh *on numerous occasions* from approximately April 2014 to approximately February 2015. This is a ten-month period spanning both before and after the entry of PTO 121 on June 17, 2014. In that time, Plaintiffs suggested the parties use a mutual expert, offered the opportunity to be present when the material was received and analyzed, and otherwise offered to make the specimen available if Ethicon wanted to have it examined. *See* Kip Petroff's (counsel for Plaintiffs') e-mail to William Gage of Butler Snow, April 28, 2014, Pls.' Ex. A, Doc. 174 at 3; Petroff e-mail to Chad Hutchinson of Butler Snow, April 28, 2014, Pls.' Ex. A, Doc. 174 at 4; Petroff-Hutchinson e-mails, June 19, 2014, Pls.' Ex. B, Doc. 174 at 12-13; Petroff e-mail to Jan Thomas and Hutchinson of Butler Snow, January 23, 2015, Pls.' Ex. A, Doc. 174 at 5; Petroff e-mail to Thomas and Hutchinson, February 3, 2015, Pls.' Ex. A., Doc. 174 at 6.

The court also concludes from its examination of the record that Dr. Iakovlev, although expressing some confusion regarding whether the specimen had been divided before it was sent to him, did not act in bad faith. *See* Dr. Iakovlev e-mail to Watkins, March 7, 2015, Pls.' Ex. G, Doc. 174 at 37-38; Dr. Iakovlev e-mail to Watkins, March 10, 2015, Pls.' Ex. G, Doc. 174 at 36-37; Watkins e-mail to Dr. Iakovlev, March 10, 2015, Pls.' Ex. G, Doc. 174 at 37; Dr. Iakovlev e-mail to Watkins, May 4, 2015, Pls.' Ex. G, Doc. 174 at 36.

Finally, the record before the court shows that Ethicon's pathology expert, Thomas C. Wright Jr., M.D., although he did not receive an unadulterated specimen, had other material available to him from the surgery including slides of the excised mesh, and was able to form

opinions and provide a report in rebuttal to Dr. Iakovlev's conclusions that the mesh specimen was rolled and degraded. *See* Expert Report of Thomas C. Wright Jr., M.D., Pls.' Ex. G, Doc. 174 at 44-63.

The MDL court's meet-and-confer order applies to both parties. Ethicon should not benefit from its own lack of diligence and, in the court's estimation, bears some level of responsibility for the parties' failure to handle the excised mesh in the fashion envisaged by the MDL court. For these reasons, and those set forth directly above, the court **denies** Defendants' Motion to Strike the Case-Specific Opinions and Testimony of Dr. Vladimir Iakovlev for Failure to Comply with PTO 121 (Doc. 161).

V. *Daubert* Motions

Also pending are Defendants' Motion to Exclude Certain Opinions of Dr. Daniel Elliott (Doc. 155), Defendants' Motion to Exclude the Case-Specific Opinions of Vladimir Iakovlev, M.D. (Doc. 158), and Plaintiffs' Motion to Exclude the General Causation Opinions of Defense Expert Christina Pramudji, M.D. (Doc. 164).

Following the MDL court's remand of this case to the undersigned, on August 6, 2020, pursuant to the court's directive, the parties filed a "Joint Status Report and Discovery/Case Management Plan." Doc. 145. On October 7, 2020, the parties filed a "Joint Chart Showing Relevant *Daubert* Filings, Ruling, and Undecided Issues." Doc. 148. In the Joint Status Report and Discovery/Case Management Plan, the parties inform the undersigned that the MDL court, as part of its coordination of the pretrial proceedings in numbered waves, has already ruled on substantive issues involving numerous experts. According to the parties:

> The Ethicon MDL Court oversaw this case and thousands of others for coordinated pre-trial proceedings. The MDL Court coordinated the pre-trial proceedings in numbered waves. This case was initially part of Wave 5, but was subsequently worked up as a part of Wave 12. Certain *Daubert* motions concerning

> both the Defendants' and Plaintiffs' designated "general" experts were fully briefed as part of earlier waves, and the Court did issue Memorandum Opinions and Orders concerning those motions in cases in those earlier waves. In the MDL Court, the parties in this case adopted by incorporation the majority of their respective and earlier wave motions and related briefs. At the time the instant case was transferred to this Court, the MDL Court had not issued any order adopting its prior rulings in this (or any) Wave 12 case. Instead the MDL Court remanded this case to this Court for all further proceedings and advised that "it is the parties' responsibility to follow the receiving court's procedure for identifying any individual motions that remain pending and in need of ruling."

Joint Status Report and Discovery/Case Management Plan 5, Doc. 145. In their Joint Chart Showing Relevant *Daubert* Filings, Ruling, and Undecided Issues (Doc. 148), the parties list the prior MDL rulings concerning challenges to case-specific and general experts that are pertinent to the case. The court has carefully reviewed the parties Joint Designation of Record (Docs. 105-123), as well as Judge Goodwin's rulings involving expert testimony, and hereby **adopts** these rulings as those of this court as have other remand courts.

It is unclear to the court whether its decision to adopt Judge Goodwin's earlier rulings on expert testimony pertinent to this matter has any impact on the issues presented in the pending *Daubert* motions (Docs. 155, 158, 164). This, coupled with the court's decision granting Ethicon's motion for summary judgment on Plaintiffs' failure to warn claims (and claims derivative thereof) and granting Ethicon's motion for summary judgment on Plaintiffs' loss of consortium claim, counsels against the court issuing a ruling on the three pending *Daubert* motions in their current iteration. Many of the parties' objections to the various witnesses have been mooted by the court's rulings and, in many instances, Plaintiffs have noted in response to Ethicon's *Daubert* motion that they will not offer their designated expert on certain categories of testimony to which objection has been made. As such, many of Ethicon's *Daubert* challenges are now moot.

In light of the foregoing developments, and in the interest of preserving scarce judicial resources, the court **denies without prejudice** Defendants' Motion to Exclude Certain Opinions

of Dr. Daniel Elliott (Doc. 155), Defendants' Motion to Exclude the Case-Specific Opinions of Vladimir Iakovlev, M.D. (Doc. 158), and Plaintiffs' Motion to Exclude the General Causation Opinions of Defense Expert Christina Pramudji, M.D. (Doc. 164).

VI. Conclusion

For the reasons stated herein, the court **grants in part** and **denies in part** Defendants' Motion for Summary Judgment (Doc. 152). The court **grants** Defendants' Motion for Summary Judgment with respect to Plaintiffs' design defect claim (sounding in both negligence and strict liability) insofar as Dr. Elliott suggests alternative (1)—a suture product, as with the Burch procedure—as a safer alternative design to the Gynecare TVT device; **denies** Defendants' Motion for Summary Judgment with respect to Plaintiffs' design defect claim insofar as Dr. Elliott suggests alternatives (2) using a pubovaginal sling (autologous, cadaveric, or xenograft), (3) using an allograft sling, like Repliform, and (4) using a lighter weight, larger pore mesh sling with less Prolene® material (other than Ultrapro) with sealed borders, as safer alternative designs to the Gynecare TVT device; and **denies** Defendants' Motion for Summary Judgment with respect to Plaintiffs' design defect claim insofar as Dr. Raybon suggests a heat-sealed large pore mesh as a safer alternative design to the Gynecare TVT device.

Further, the Court **grants** Defendants' Motion for Summary judgment on Plaintiffs' negligence-based and strict-liability-based failure to warn claims, as well as their derivative claims of fraud and negligent misrepresentation, and **dismisses** these claims **with prejudice**. In addition, the Court **grants** Defendants' Motion for Summary judgment with respect to Plaintiffs' loss of consortium claim and **dismisses** this claim **with prejudice**.

The Court **dismisses with prejudice** the following claims, as Plaintiffs abandoned or withdrew them at the MDL stage: strict liability—manufacturing defect (Count II); negligence and

gross negligence—manufacturing defect (Counts I and XIV); strict liability—defective product (Count IV) (except to the extent it is encompassed in Plaintiffs' design defect or failure to warn claims); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent infliction of emotional distress (Count X); breach of express and implied warranties (Counts XI and XII); violation of consumer protection laws (Count XIII); and unjust enrichment (Count XV). Insofar as Defendants seek summary judgment on these claims, the Court **denies as moot** Defendants' Motion for Summary Judgment.

The court **denies** Defendants' Motion to Strike the Case-Specific Opinions and Testimony of Dr. Vladimir Iakovlev for Failure to Comply with PTO 121 (Doc. 161).

Finally, the court **denies without prejudice** Defendants' Motion to Exclude Certain Opinions of Dr. Daniel Elliott (Doc. 155), Defendants' Motion to Exclude the Case-Specific Opinions of Vladimir Iakovlev, M.D. (Doc. 158), and Plaintiffs' Motion to Exclude the General Causation Opinions of Defense Expert Christina Pramudji, M.D. (Doc. 164).

Remaining for trial are Plaintiffs' negligence and strict liability claims for design defect (Counts I and V), and Plaintiffs' strict liability—defective product claim (Count IV) (but only insofar as it is encompassed in Plaintiffs' design defect claim). The court will set the trial of this case and pretrial deadlines by separate order.

This case was filed on September 7, 2012, approximately ten years ago. Given the court's rulings, which have consumed an inordinate amount of scarce judicial resources, the complexity of this case, and the time the case has been pending before this court and the MDL court, the court strongly encourages the parties to consider an expeditious resolution of the pending claims. As for the remaining issues, the court notes that this is not an "open-and-shut case" for either side, and a jury may find it difficult to grasp the highly technical

nature of the case. As the court has made its definitive rulings, the parties are in a superior position to assess their relative strengths and weaknesses regarding the remaining claims. Moreover, the court advises the parties that because of the impact of the COVID Pandemic and that the criminal cases take precedence over the civil cases, this matter would not be tried until late 2023. The court directs the parties to inform it no later than April 1, 2022, whether they can resolve this action without further court involvement.

It is so ordered this **16th** day of **March, 2022**.

Sam A. Lindsay
United States District Judge